Message

To: Heather King [hking@theranos.com]; Elizabeth Holmes [eholmes@theranos.com]
Subject: RE: CMS statement (privileged and confidential)

Overall DRAFT statement on PT/INR FOR WSJ: The new lab director approved enhanced reagent management procedures, as well as improved quality control procedures, to address issues raised by CMS concerning the PT/INR test, such as accounting for the third party manufacturer's changes to the characteristics of a certain reagent lot. The lab investigated all PT/INR issues raised by CMS, has notified any potentially affected patients, and has no reason to believe that these issues have affected patients' health.

From: Heather King
Sent: Monday, March 07, 2016 1:59 PM
To: Sunny Balwani <sbalwani@theranos.com>; Elizabeth Holmes <eholmes@theranos.com>
Subject: RE: CMS statement (privileged and confidential)

Yes, I think the plan is that we:

- Direct the WSJ to our already-posted web statement (IF TAKE OUT THE PT/INR BULLET THEN WE COULD ADD IT HERE]
- Here are the WSJ's questions on CMS. Our statement would deal with all but those I highlight, with the context I had sent this weekend, in case we want to say anything more.

Overall DRAFT statement on PT/INR FOR WSJ: The new lab director approved enhanced reagent management procedures, as well as improved quality control procedures, to address issues raised by CMS concerning the PT/INR test, such as accounting for the third party manufacturer's changes to the characteristics of a certain reagent lot. The lab investigated all PT/INR issues raised by CMS, has notified any potentially affected patients, and has no reason to believe that these issues have affected patients' health.

Potential answers to their questions (highlighted is where we may want to answer; all others are to be ignored)

1. It's our understanding that Theranos's Newark lab performed prothrombin time tests. If true, what machines did the lab perform these tests on last year? Was one of the machines a Siemens machine?

[BSF: The 2567 says this test occurred in 2015 and was run on the Siemens BCS XP.] "The tests were performed on a third party machine."

2. Did Theranos perform quality-control checks of the prothrombin time test last year? If so, was one of the products the Newark lab used to perform quality-control checks of the prothrombin time test called "Ci-Trol Coagulation Control Level 3," a product also made by Siemens?

[BSF: This is the QC material that was associated with the PT/INR deficiency. Note, however, that the 2567 refers to it as "Citrol 3". It does not say "Ci-Trol Coagulation Control Level 3," but he could have obtained the product name through an Internet search.] NO NEED TO ANSWER

3. Did the CMS inspectors find that the Newark lab's prothrombin time test repeatedly produced erratic results during quality-control checks with Ci-Trol 3 over a nearly six-month period from April 1 to Sept. 23, 2015?

[BSF: This date range matches what's in the CMS 2567, and this is clearly asking about the deficiency described in D5481, which indicates that QC was often out or greater than 2SD.] NO NEED TO ANSWER

4. Did the CMS inspectors specifically find that the results from those quality-control checks frequently deviated by more than two standard deviations from the range the lab had established as acceptable?

[BSF: This is consistent with D5481, which found that 25 of 32 days were greater than -2SD.] NO NEED TO ANSWER

5. Did the CMS inspectors find that the prothrombin time quality-control checks failed seven times in a single day?

[BSF: This is consistent with D5481, which identifies 9/7/15 as a day when QC failed 7 times.] NO NEED TO ANSWER

6. Did the CMS inspection report note that "on 25 of 32 days, Ci-Trol 3 was not re-run when the QC value was greater than – 2SD"?

[BSF: Except for saying "Ci-trol 3" instead of "Citrol 3," this is a direct quote from D5481 in the 2567.] NO NEED TO ANSWER

7. It is our understanding that the agency's findings about the prothrombin time quality-control lapses are contained in a section of the CMS inspection report entitled, "Failure to Ensure that QC Test Results Met the Lab's Criteria for Acceptability." Is that accurate?

[BSF: This isn't exactly a title heading, but appears to come from the Analytic Condition (D5400), which summarizes various supporting Standard Deficiencies, including the PT/INR QC deficiency: "failed to ensure that QC tests results met the laboratory's criteria for acceptability for Prothrombin Time/International Normalized Ratio and the Theranos Proprietary System (TPS) prior to reporting patient test results." If that's where this is coming from, it's notable that he's not mentioning the TSPU issue. There are two additional lines like this in D5481, but they do not appear close enough to be the one he's discussing. In addition, the Condition-level description, which cited D5481, could be confused with a title.] ANSWER: "NO"

8. It is our understanding that the prothrombin time quality-control lapses were among the hematology deficiencies at the Newark lab that CMS deemed to "pose immediate jeopardy to patient health and safety." Is that accurate?

[BSF: This is reflected in the Hematology Condition (D5024), which says the lab failed to "ensure QC for PT/INR was acceptable prior to reporting patient test results

(see 05481)."] NO NEED TO ANSWER

9. It is our understanding that Theranos's Newark lab continued to perform the prothrombin time test on live patient samples despite erratic quality-control results during the six-month period cited above. Is that accurate? If so, did the patients it performed the test on during this period number 81? ANSWER: "NO"

[BSF: The 2567 says that "81 patients were reported." However, in the patient assessment enclosed with the response, the lab says that there were 83 tests reported for 39 patients during this period.]

10. If Theranos performed the prothrombin time test on patient samples despite erratic quality-control results, has it contacted these patients and/or their doctors to inform them of the quality-control problems found by the CMS inspectors? If so, has it done so in writing or on the phone or by some other means? If not, does Theranos intend to contact these patients or their doctors?

[BSF: This may suggest he hasn't seen the full 2567 report or even all of the deficiencies related to PT/INR because (D5821) discussed 13 of the 83 corrected reports that were issued during the survey, and noted that 5 of the 13 were faxed. It also notes that the Technical Supervisor told CMS that "all authorized persons were notified of the error in PT/INR results."] NO NEED TO ANSWER IF WE SEND THE PROPOSED STATEMENT ABOVE OR SOMETHING LIKE IT, WHICH ADDRESSES THIS.

11. If Theranos performed the prothrombin time test on patient samples despite erratic quality-control results, has the company investigated whether any of the prothrombin time results reported to those patients had undesirable health consequences?

[BSF: We say in our response that we've conducted a patient impact assessment. However, we do not say whether we investigated whether any of the originally reported results "had undesirable health consequences." This appears to be a question that's not based on something a source said. Such an investigation is not what's required; however, it is something that a patient or physician could tell the lab after receiving the corrected report.] NO NEED TO ANSWER IF WE SEND THE BROAD STATEMENT ABOVE, WHICH DEALS WITH THIS.

12. Did the CMS inspectors also find that the Newark lab used expired reagents for some of the prothrombin time tests?

[BSF: This is the CMS finding in D5413 #2 and D6094. The vagueness of his question as to time may indicate that he doesn't have the specific portions of the report, which say that the reagent was used from March to September 2015.] NO NEED TO ANSWER IF WE SEND THE BROAD STATEMENT ABOVE.

13. It is our understanding that the CMS inspectors found that the Newark lab's director did not have responsibility for the lab's quality-assurance and -control program and that the QAQC manager in charge of the program was unqualified. Is that accurate?

[BSF: This relates to CMS findings (D6079, D6093 #1, D6094 #1). D6079 says that the "evaluating and monitoring the QA and QC programs was solely the QA/QC Manager's responsibility." The deficiencies also say that the QA/QC Manager was not qualified for this role, and that the LD failed to delegate these duties to a qualified TS.] NO NEED TO ANSWER IF WE SEND THE BROAD STATEMENT ABOVE + REFER THEM TO OUR WEBSITE STATEMENT. IF WE DON'T WE COULD JUST ADD SOME OF OUR BROAD LANGUAGE HERE ON THE POLICES PUT IN PLACE AND SUCH. WE COULD PULL FROM OUR WEB STATEMENT FOR THIS.

14. Has CMS indicated to Theranos whether the correction plan the company submitted to the agency last month is satisfactory?

[BSF: A knowledgeable source would have been able to provide him with the answer.] NO NEED TO ANSWER

15. Has Theranos asked CMS not to release the agency's inspection report on the grounds that it contains trade secrets? If so, has the agency responded to this request?

[BSF: He may be guessing based on Theranos past stances on the subject, but might be referring to the request to redact.] NO NEED TO ANSWER

16. Has Walgreens asked to see the CMS inspection report and Theranos's correction plan? Has Theranos provided either to Walgreens?

YES, THERANOS HAS SHOWN THE REPORT AND PLAN AND EVIDENCE OF CORRECTION TO WALGREENS. (I think it makes the partnership with WAG look much stronger to tell WSJ that we showed both the report and the plan of correction to WAG. They are obviously going to ask WAG anyway whether they've seen it, so its not like we are tipping them off. And I think it makes us look like a more responsible partner to proactively go show our partner these things and to be transparent about it)

17. Theranos has told several media organizations that it would host a roundtable of experts who would be shown its technology and given permission to comment about it. Has this roundtable happened? YES.

We look forward to your answers to these questions and, as always, to any information you think we ought to consider.

Thanks in advance,

John

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From: Sunny Balwani
Sent: Monday, March 07, 2016 12:18 PM
To: Heather King <hking@theranos.com>; Elizabeth Holmes <eholmes@theranos.com>
Subject: RE: CMS statement (privileged and confidential)

so the plan is not to respond to the journal and just post this on our web?

From: Heather King
Sent: Monday, March 07, 2016 12:11 PM
To: Elizabeth Holmes <eholmes@theranos.com>; Sunny Balwani <sbalwani@theranos.com>
Subject: CMS statement (privileged and confidential)

Attorney Client Communication/Privileged and Confidential

Per my legal advice and BSF's, please see the current draft of the CMS statement for your review. Sunny – I believe this requires you primarily; it reflects what EH told me earlier this morning that she wanted edited. Once I hear from you, I'll get it to King right away to try to get his eyes on it.